

Meeting Notes
Pigment Violet 29 Test Studies Update with Sun Chemical Corporation
Phone Conference
June 28th, 2017

Attendance:

Hannah Braun (EPA-CCD)
Lorraine Passe (EPA-CCD)
Alie Muneer (EPA-RAD)
Jafrul Hasan (EPA-RAD)
Robert Mott (Sun Chemical Corporation)

Notes:

- EPA informed Sun Chemical about the effort to collect the full FDA petition about Pigment Violet 29's use as a food additive in polymers created by BASF Corporation.
 - EPA originally only had an excerpt of the petition
 - EPA contacted the FDA to see if there was more, especially if they had full study reports
 - FDA responded by sending the full petition which included only two full study reports for an AMES test and water solubility test
- EPA seeks full study reports for studies found in the ECHA database from the REACH registration dossier
 - Sun Chemical states that neither the Sun Chemical U.S. subsidiary nor the parent company in the Netherlands own any of the studies in ECHA
 - A non-disclosed company in Europe is the owner
 - Sun Chemical will communicate with the REACH consortia and owners of the studies specifically to get the EPA full study reports it requests
- Before any studies are given to the EPA, an agreement must be in place between the EPA and owners of the studies in order to protect this intellectual property.
 - The owners of the studies are concerned that if they submit the studies in full now, then EPA will make the studies publically available and anyone would be able to use these studies for financial gain without compensation to the original creators of the data.
 - Sun Chemical would like to know what EPA can do to protect the intellectual property.
 - Sun Chemical would present the EPA proposal to the owners of the studies.
 - Dr. Mott offered several proposals that he believes the data owners would agree to, and would like to present these options to the data owners:
 1. EPA to make robust summaries available publically in the docket
 - a. Industry preferred because this is how it is already available in ECHA
 2. EPA to make redacted versions of the full studies available publically in the docket
 3. EPA to add a watermark to every page of the full study reports available publically in the docket
- EPA can contact Steve Camenish (BASF Corp) or Robert Mott with proposal
 - Mr. Camenish will be traveling July 8-24th
- EPA probably won't get full reports until September because PhD's travel in the summer months